



PATENT

1651

Case Docket No. UPTINC.015A

Date: November 19, 2001

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In re application of : V. Bronshtein
App. No. : 09/254,563
Filed : March 5, 1999
For : SHELF PRESERVATION OF CELLS,
TISSUES, ORGANS AND
ORGANISMS BY VITRIFICATION
Examiner : S. Saucier
Art Unit : 1651

I hereby certify that this correspondence and all
marked attachments are being deposited with the
United States Postal Service as first class mail in an
envelope addressed to: Assistant Commissioner for
Patents, Washington, D.C. 20231, on

November 19, 2001

(Date)

Che S. Chereskin
Che Swyden Chereskin, Ph.D., Reg. No. 41,466

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

Transmitted herewith is the following in the above-identified application.

(X) A Preliminary Amendment for Continued Prosecution Application in 5 pages with Attachments A and B.

The fee has been calculated as shown below:

CLAIMS AS FILED						
	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST NO. PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE	ADDITIONAL FEE
Total Claims	15	—	24	= 0 ×	\$9	= \$0
Independent Claims	1	—	4	= 0 ×	\$42	= \$0
If application has been amended to contain multiple dependent claim(s), then add					\$140	= \$0
Time Extension Fee						\$0
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT						\$0

(X) The present application qualifies for small entity status under 37 C.F.R. § 1.27.

(X) Return prepaid postcard.

(X) Please charge any additional fees, including any fees for additional extension of time, or credit
overpayment to Deposit Account No. 11-1410.

Che S. Chereskin
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Registration No. 41,466
Agent of Record

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UPTINC.015A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Bronshtein, V.) Group Art Unit : 1651
Appl. No. : 09/254,563)
Filed : March 5, 1999)
For : SHELF PRESERVATION OF CELLS,)
TISSUES, ORGANS AND)
ORGANISMS BY VITRIFICATION)
Examiner : Saucier, S.)

**PRELIMINARY AMENDMENT FOR
CONTINUED PROSECUTION APPLICATION**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Preliminary to examination on the merits, enter the Amendment filed under 37 C.F.R. § 1.116 on April 4, 2001.

REMARKS

As a result of this preliminary amendment, Claims 1, 7, 9, 10, and 12 have been amended as set forth in the Amendment under 37 C.F.R. § 1.116 of April 4, 2001. Additionally, Applicant would like to provide the following remarks in response to the Advisory Action of April 23, 2001.

Response to Advisory Action and Rejection under 35 U.S.C. § 112, second paragraph

The Examiner asserted in the Advisory Action that "Applicant's explanation of "refrigeration" temperature being from 10 to -70C does not appear to have support in the supplied definition. Also, Applicant's claims are open to further lowering of temperature."

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In response, Applicant submits herewith Attachments A & B. Attachment A describes a temperature range of International Cold Storage outdoor refrigeration units. The temperature range given is from -30°F to +80° F which corresponds to about -34° C to 27° C.

Attachment B describes thermostats for refrigeration units. The temperature range is from -67 to 248° F. This corresponds to about -55° C to about 120° C.

It is submitted that one skilled in the art would understand the meaning of the term “refrigeration temperature” as the temperature at which refrigerators operate. The temperature at which refrigerators operate is generally known or may be easily determined as evidenced by Attachments A & B.

In view of Applicant’s arguments and Attachments A & B, reconsideration and withdrawal of this ground of rejection is respectfully requested.

New matter

Claims 1, 4-10, 12-17, 25, and 26 are rejected under 35 112, first paragraph as containing new matter. Applicant gratefully acknowledges the indication by the Examiner in the Advisory Action of 4/23/01 that this ground of rejection had been overcome by the Amendment under 37 C.F.R. § 1.116, now entered.

Rejections under 35 U.S.C. §102

Claims 1, 4-7, 16, and 25 were rejected under §102(b) as being anticipated by Titterington et al. This reference teaches immersion of specimens in liquid nitrogen (-196° C) in the presence of sucrose (a non-permeating co-solute), glycerol (a permeating cryoprotectant) and Percoll (a non-permeating cryoprotectant). However, the disclosure of Titterington et al. is limited to rapid freezing to -196° C. Titterington et al. does not teach dehydrating a specimen in a permeating cryoprotectant, a non-permeating co-solute and a non-permeating polymeric cryoprotectant, and then vitrifying the dehydrated specimen by cooling to a refrigerated or higher storage temperature, as recited in present Claim 1. As set forth above in response to the rejection under 35 U.S.C. §112, second paragraph, Applicant’s claims encompass refrigeration temperatures, that is, temperatures obtainable by the use of a refrigerator. Consequently, Applicants’ claims cannot be anticipated by a teaching that includes freezing to -196°C. The cited art teach methods which include freezing at temperatures of -160° C to -196° C. Clearly such temperatures are not in the range of “refrigeration” temperature as claimed in view of Attachments A & B discussed above.

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Reconsideration and withdrawal of this ground of rejection is respectfully requested.

Claims 1-6, 9, 10, 16, 18-24 and 25 remain rejected under 35 U.S.C. § 102 as being anticipated by Rall et al. Claims 18-24 have been canceled.

Rall et al. discloses progressive or step-wise cooling of embryos down to -196°C (liquid nitrogen). Applicant's claims are drawn to vitrification at refrigeration temperatures. See the discussion above regarding Applicant's definition of refrigeration. Rall et al. cannot anticipate Applicant's claims as the disclosure of Rall et al. is drawn to the use of much lower temperatures.

In view of Applicant's arguments, withdrawal of this ground of rejection is respectfully requested.

Claims 1, 4-7, 9, 12-16, 25 and 26 remain/are rejected under 35 U.S.C. § 102 (b) as anticipated by U.S. Patent No. 5,364,756.

The '756 patent teaches the use of very low temperatures, e.g., -196°C (see col. 17 lines 15-39 and Example 4 which teaches temperatures of -160°C). Again, Applicant's claimed method is not drawn to the use of such low temperatures. Applicant's method is directed to the use of temperatures which can be achieved with the use of a refrigerator. Temperatures of -160°C to -196°C cannot be achieved by a refrigerator. Consequently, Applicant's claims are not anticipated by the '756 reference.

Withdrawal of this ground of rejection is respectfully requested.

Claims 1, 4-7, 9, 10, 12-17, 25, and 26 remain rejected under §102(e) as anticipated by U.S. Patent No. 5,800,978 to Goodrich. As noted by the Examiner, Goodrich discloses numerous cryopreservation solutions comprising permeating cryoprotectants, non-permeating co-solutes and non-permeating cryoprotectants. Goodrich also teaches freezing cells in these cryopreservation solutions, and in some cases (See e.g., Example 6), subsequent dehydration by sublimation. However, Goodrich does not disclose vitrification as claimed by Applicant. Goodrich et al disclose a method which "provides a multi-component aqueous cryopreservative system(s) that at appropriate temperatures form partially crystalline mixtures of water ice with interspersed regions of a separate amorphous glass phase" (col. 4, lines 15-18). Also, in contradistinction to Applicant's claimed method, Goodrich teaches against the use of DMSO

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(col. 3, lines 25-26). Consequently, the disclosure of Goodrich is drawn to a different method than the method claimed by Applicant.

The Examiner argues that Goodrich inherently teaches the claimed method because Goodrich teaches Applicant's three classes of compounds (Paper No. 8, page 8, lines 1-2). However, as noted above, the compounds taught by Goodrich are not synonymous with the compounds of the presently claimed invention. Goodrich teaches away from the use of DMSO. Furthermore, Goodrich does not teach a non-permeating co-solute. To the extent that the compounds used by Goodrich may coincidentally fall into the categories taught by Applicant, it is noted that the specific combinations taught by Goodrich do not correspond to the specific components taught by Applicant. For example, the Examiner cites buffer No.8 of Table 2, maintaining that the glucose component corresponds to the permeant component (Paper No. 8, page 7, lines 16-18). However, glucose is not one of the compounds listed in Applicant's claim 4 as a permeant component.

Consequently, Goodrich does not teach all of the elements of Applicant's claimed invention and the rejection under 35 U.S.C. § 102 may be properly withdrawn.

Rejections under 35 U.S.C. §103

Claims 1, 4-10, 12-16, 25-26 are/remain rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. 5,364,756 in view of 5,217,860 taken with U.S. 4,865,871 or Rall et al. and U.S. 5,879,876.

The primary reference fails for the reasons given above in the response to the rejection under 35 U.S.C. § 102. The '756 patent teaches the use of very low temperatures, e.g., -196°C (see col. 17 lines 15-39 and Example 4 which teaches temperatures of -160°C). Again, Applicant's claimed method is not drawn to the use of such low temperatures. Applicant's method is directed to the use of temperatures which can be achieved with the use of a refrigerator. Temperatures of -160°C to -196°C cannot be achieved by a refrigerator. The cited art teach methods which include freezing at temperatures of -160° C to -196° C. Clearly such temperatures are not in the range of "refrigeration" temperature as claimed in view of Attachments A & B discussed above.

None of the cited references alone or in combination teach or suggest vitrifying a dehydrated specimen by cooling to a refrigeration or higher storage temperature as recited in

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claim 1. The '860 disclosure teaches temperatures of -135 °C (col. 24, line 37). The '871 disclosure teaches the use of temperatures of -196°C (col. 9, lines 40-42). The '876 disclosure teaches "ultra low temperature" (col. 15, lines 7). None of the cited references teach or suggest vitrification at higher (refrigeration) temperatures.

Since all claims depend from claim 1, which is neither taught nor suggested by the cited references as discussed above, the invention defined in claims 4-10, 12-16, 25 and 26 is also patentably distinguished from the references, alone or in combination. Applicant respectfully requests the withdrawal of the rejection.

Conclusion

Should there be any questions concerning this application, the Examiner is invited to contact the undersigned agent at the telephone number appearing below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: Nov. 19, 2001

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